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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,879	08/12/2002	Pieter Cornelis Langeveld		1306

7590 01/28/2008

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EXAMINER	
ZEMAN, ROBERT A	

ART UNIT	PAPER NUMBER
1645	

MAIL DATE	DELIVERY MODE
01/28/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/089,879	LANGEVELD ET AL.	
	Examiner	Art Unit	
	Robert A. Zeman	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6 and 12-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 12-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8-22-2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment and response filed on 8-22-2007 are acknowledged. Claims 1 and 14 have been amended. Claims 1-6 and 12-20 are pending and currently under examination.

Information Disclosure Statement

The Information Disclosure Statement filed on 8-22-2007 has been considered. An initialed copy is attached hereto.

Claim Rejections Withdrawn

The rejection of claims 1-6 and 12-16 under 35 U.S.C. 102(b) based upon a public use or sale of the invention is withdrawn.

The rejection of claims 1-6 and 12-16 under 35 U.S.C. 103(a) as being unpatentable over Charm et al. (U.S. Patent 5,354,663) is withdrawn in lieu of the rejections set forth below.

New Grounds of Rejection

35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6 and 12-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Charm et al. (U.S. Patent 5,354,663) in view of Inglis et al. Journal Assoc. Off. Anal. Chem. Vol. 61, No.5, 1978, pages 1098-1102 - IDS). Applicant's arguments as they pertain to the instant rejection are addressed below.

Applicant argues:

1. Heating the sample prior to the addition of the test would coagulate the egg sample.

2. The prior art teaches away from relying on diffusion of the antimicrobial residue as evidenced by Inglis et al. and Katz et al.

3. The instant has the unexpected advantage that after heat inactivation the antimicrobial residues diffuse from the contacted sample and incubation takes place directly after heating.

4. Inglis et al. and Katz et al. are evidence that the prior art recognized that the coagulation of egg was an obstacle to recovering antimicrobial residues.

5. All the heating times described in Charm et al. are 2 minutes or less. There is no acceptable explanation as to why the skilled artisan would prolong heating if 2 minutes were sufficient to destroy the natural inhibitors present in the sample.

With regard to Point 1, the combination of references does not preclude the coagulation of the egg sample.

With regard to Points 2 and 4, Inglis et al. disclose that the heat treatment at 85 °C for 15 minutes by itself was effective in eliminating non-specific inhibition (see page 1100 of Inglis et al.).

With regard to Point 3, Applicant has provided no *evidence* that the method of the instant invention is superior to the method of the combined references. It should be noted that the "ice bath cooling" of the "heated sample" in itself would drastically reduce the diffusion rate.

With regard to Point 5, contrary to Applicant's assertion, the skilled artisan would extend the heating period beyond the 2 minutes

Charm discloses a test method for the determination of antimicrobial drugs in **food samples**, in which the test method includes placing a sample into a container and heating the sample to a temperature sufficiently high to destroy the natural inhibitors in the sample. The method further comprises adding a test microorganism to the sample, rapidly heat shocking said mixture; allowing said mixture to cool to (see example 1) to 80 °C to 85 °C and incubating the mixture containing the sample and the test to determine whether or not microbial growth occurs (see column 3, line 27, to column 4, line 10, in particular, column 3, lines 32-35).

Charm et al. differs from the instant invention in that they do not explicitly disclose the mixing of the test composition (spores) and the sample (e.g. eggs) prior to the heating steps nor do they disclose the temperature range and duration of heating encompassed by claims 5.

Inglis et al. disclose that heating a egg sample to 85 °C for 15 minutes was effective in eliminating non-specific inhibition (see page 1100) and that antibiotic residues can be detected in samples comprising homogenized raw eggs (see page 1099).

Consequently, it would have been obvious for one of ordinary skill in the art to heat a homogenized raw egg sample to 85 °C for 15 minutes prior to assaying in order to get rid of non-specific inhibition caused by substances such as lysozyme.

Moreover, it would have been obvious for one of ordinary skill in the art to combine the sample with the test reagent prior to heating in order to streamline the method. The resulting method would reduce the need to handle hot samples etc. It would have been equally obvious to homogenize any solid food sample in order to ease sample handling.

One would have had a reasonable expectation of success as the disclosed method discloses the addition of the test composition to a heated sample and the test composition is not heat labile.

Claims 1-6 and 12- are rejected under 35 U.S.C. 103(a) as being unpatentable over Geijp et al. (Abstract book "Third International Symposium of Hormone and Veterinary Drug Residue Analysis, Brugge",1998). in view of Inglis et al. Journal Assoc. Off. Anal. Chem. Vol. 61, No.5, 1978, pages 1098-1102 - IDS).

The method that constitutes the instant invention is disclosed in the instruction sheet for the Premi®Test which was publicly disclosed prior to the priority date of the instant application as evidenced by Geijp et al.. The procedure set forth in said instruction sheet differs from the instant invention in that they don't explicitly disclose the use of an uncoagulated egg sample or

the heating of the sample to 85 °C for up to 15 minutes prior to assaying in order to get rid of non-specific inhibition caused by substances such as lysozyme.

Inglis et al. disclose that heating a egg sample to 85 °C for 15 minutes was effective in eliminating non-specific inhibition (see page 1100) and that antibiotic residues can be detected in samples comprising homogenized raw eggs (see page 1099).

Consequently, it would have been obvious to the skilled artisan to modify the Premi®Test method to test egg samples and to include a heating step to get rid of the non-specific inhibition associated with egg samples. Moreover, given that the method for assaying food samples for antibiotic residues was known; that homogenized egg samples had been assayed in similar assays; and that lysozyme (which was responsible for non-specific inhibition) can be inactivated by heating a homogenized egg sample for 15 minutes at 85 °C, the skilled artisan would have had a reasonable expectation of success of detecting antibiotic residues in egg samples after heating said samples [see *KSR International Co. v. Teleflex Inc.*, No. 04-1350 (U.S. Apr. 30, 2007)].

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (571) 272-0866. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on (571) 272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov.

Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ROBERT A. ZEMAN
PRIMARY EXAMINER
January 9, 2008